

Remarks

Amendments to the Claims

Clarifying amendments, based on the original claim language, are made to claims 1, 4-13, 16-18, 26-28, 30-35, 40, 41, 43-46, 50-52, 57, 60, 61, 66, 68, 71, 73, 79, 80, and 84-90. The amendments do not add new matter.

Amendments to the Specification

A text file containing a formal sequence listing accompanies this paper. The sequence listing contains only sequences present in the application as filed and does not add new matter. The specification is amended to incorporate the sequence listing by reference and to insert sequence identifiers throughout the specification. None of these amendments adds new matter.

Objections to the Claims

The Office Action objects to claims 10, 12, 16, 27, 84, and 88. This amendment addresses the objections as follows.

Claim 10 as amended does not contain the phrase “analogous to the analogous.”

Claims 12, 16, and 84 are amended to correct grammatical errors.

Claims 27 and 88 are amended to define the acronyms “Prot,” “Int,” and “RT,” and the protein names are amended as suggested in the Office Action.

Please withdraw the objections.

Rejection of Claims 18 and 26 Under 35 U.S.C. § 112 ¶ 2

Claims 18 and 26 stand rejected as indefinite under 35 U.S.C. § 112 ¶ 2 for lacking antecedent basis for the recitation of “alteration or mutation.” Claim 18 is amended to depend from claim 17, which provides antecedent basis for the recitation of “alteration or mutation.” Please withdraw the rejection.

Rejection of Claims 1, 3, 4, 7, 8, 10-12, 16, 27, 28, 32-34, 80, 82, 84, 88, and 89 Under 35 U.S.C. § 102(b)

Claims 1, 3, 4, 7, 8, 10-12, 16, 27, 28, 32-34, 80, 82, 84, 88, and 89 stand rejected under 35 U.S.C. § 102(b) as anticipated by Barnett.¹ Applicants respectfully traverse the rejection.

To anticipate a claim, a reference must teach every element of the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Each of the rejected claims recites a composition comprising two components: a polynucleotide component and a polypeptide component. Barnett teaches neither a single composition containing both of these recited components nor administration of such a composition. Rather, Barnett teaches administration of DNA followed by administration of protein (“DNA prime/protein subunit boost immunization; see Abstract, line 10, and the Discussion).

On page 869, col. 2, Barnett describes preparation of plasmids and recombinant protein, but does not teach a composition comprising the plasmids and protein. On page 879, Barnett teaches immunization of BALB/c mice “with 100 µg of plasmid DNA encoding Env gp120 from three different strains of HIV-1,” with a second dose (a first boost) administered eight weeks

¹ Barnett *et al.*, “Vaccination with HIV-1 gp120 DNA induces immune responses that are boosted by a recombinant gp120 protein subunit,” *Vaccine*. 1997 Jun;15(8):869-73.

later. Paragraph bridging columns 1 and 2. Then, at 16 weeks, the mice received another boost, “this time with an HIV-1 subtype-specific recombinant gp120 protein subunit adjuvanted with the novel oil-in-water emulsion, MF59.” Col. 2, first full paragraph.

Barnett does not teach every element of claims 1, 3, 4, 7, 8, 10-12, 16, 27, 28, 32-34, 80, 82, 84, 88, and 89. Barnett therefore does not anticipate the claims. Please withdraw the rejection.

Rejections Under 35 U.S.C. § 103(a)

Claims 13, 17, 18, 26, 79, and 85-87 stand rejected as obvious under 35 U.S.C. § 103(a) as unpatentable over Barnett in view of Aldovini (U.S. Pat. No. 5,861,282) and Surman.² Claims 13-15 stand rejected as obvious under 35 U.S.C. § 103(a) as unpatentable over Barnett in view of Corbet.³ Claims 30 and 31 stand rejected as obvious under 35 U.S.C. § 103(a) as unpatentable over Barnett in view of Sailaja.⁴ Applicants respectfully traverse all three rejections.

When determining whether a claim is obvious, an examiner must make “a searching comparison of the claimed invention—including all its limitations—with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). Thus, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985, C.C.P.A. 1974).

² Surman *et al.*, “Localization of CD4+ T cell epitope hotspots to exposed strands of HIV envelope glycoprotein suggests structural influences on antigen processing,” Proc Natl Acad Sci U S A. 2001 Apr 10;98(8):4587-92.

³ Corbet *et al.*, “Construction, biological activity, and immunogenicity of synthetic envelope DNA vaccines based on a primary, CCR5-tropic, early HIV type 1 isolate (BX08) with human codons,” AIDS Res Hum Retroviruses. 2000 Dec 10;16(18):1997-2008.

⁴ Sailaja *et al.*, “Long-term maintenance of gp120-specific immune responses by genetic vaccination with the HIV-1 envelope genes linked to the gene encoding Flt-3 ligand,” J. Immunol. 2003 Mar 1;170(5):2496-507.

Each of the rejections relies on Barnett as the primary reference. As explained above in connection with the rejection under 35 U.S.C. § 102(b), Barnett does not teach or suggest a single composition containing both a polynucleotide component encoding an HIV immunogenic peptide and an analogous HIV immunogenic polypeptide. None of Aldovini, Surman, Corbet, or Sailaja teaches or suggests including both of these components in a single composition.

Obviousness requires at least a suggestion of all of the features in a claim. See *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003). As the Supreme Court stated in *KSR Int'l v. Teleflex Inc.*, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” 550 U.S. 398, 418 (2007), citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). The Office Action does not articulate a reason why the cited combination of references would have motivated one of ordinary skill in the art to prepare a composition comprising the recited polynucleotide and polypeptide components. The Office Action therefore does not make a *prima facie* case that any of claims 13-15, 17, 18, 26, 30, 31, 79, and 85-87 is obvious. Please withdraw the rejections.

Respectfully submitted,
BANNER & WITCOFF, LTD.
/Lisa M. Hemmendinger/

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By: _____
Lisa M. Hemmendinger
Reg. No. 42,653

Customer No. 22907
202-824-3000